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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,062	06/20/2001	Herbert Lapidus	364.31	1692

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FITZPATRICK CELLA HARPER & SCINTO  
30 ROCKEFELLER PLAZA  
NEW YORK, NY 10112

EXAMINER

YU, GINA C

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/884,062

Applicant(s)

LAPIDUS, HERBERT

Examiner

Gina C. Yu

Art Unit

1617

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23, 26, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 14, the term "polyethylene glycol 23M" is vague and confusing. One having ordinary skill in the art would not readily apprehend the meaning of the term nor is there support for that limitation in the specification.

The term "stable" in claims 1-23, 26, and 27 is a relative term which renders the claim indefinite. The term "stable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in-
  - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application

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published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 1, 2, 5, 6, 11, 12, 17, 19, 23-25 are rejected under 35 U.S.C. 102(a) (b), and (e) as being anticipated by Fowler et al. (US 5635469) ("Fowler")

Fowler teaches non-aerosol foam producing products for personal cleansing. Examples illustrate foaming composition comprising water, surfactants, and foam stabilizer such as alkylene glycol and glycerol. See Example V. The concentrations of the components are also met. The limitation on "suitable for use as a vaginal or hemorrhoidal wipe" is viewed as an intended use which art recognizes suitability for intended purposes. See MPEP 2144.07.

2. Claims 1-3, 5-7, 11, 12, 14, and 23-25 are rejected under 35 U.S.C. 102(a) (b), and (e) as being anticipated by Jorgensen et al. (EP 1055425 A2) ("Jorgensen").

Jorgensen teaches mild, aqueous foamable skin cleanser comprising triethanolamine cocoyl glutamate, glycerin, and water See Examples. The limitation on "suitable for use as a vaginal or hemorrhoidal wipe" is viewed as an intended use.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-13, 17-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1-27 are in view of Singh et al. (US 5858371) ("Singh") in view of Pregozen (US 5141803), Jorgensen et al. (EP 1055424 A2) ("Jorgensen"), and Fowler.

Singh teaches pharmaceutical composition for treating anorectal and colonic diseases such as hemorrhoid that may be formulated in the form of foams, aerosols, sprays, or medicated pads. See abstract; col. 3, lines 25 – 28; col. 4, lines 41 – 44. The reference teaches that for foam and spray formulations, one or more aqueous and nonaqueous solvents, surfactants and stabilizing agents may be added. See col. 5, lines 11-13; col. 4, lines 1 –8; see instant claim 1. The actives of instant claims 21-23 are disclosed in col. 3, line 59 –col. 4, line 40. See col. 4, lines 1-5 for using glycerin in aqueous solution, cocoa butter, polyethylene glycol and propylene glycol as protectants. See instant claims 8, 12, and 14.

While Singh lacks explicit mention of disposing the foam on bathroom tissue, in view of teaching of formulating the invention into a medicated pad, it would have been obvious to one having ordinary skill in the art would have used a suitable substrate to apply the composition to the effected area. See instant claim 26 and 27. Singh also fails to teach the specific types or the concentration of the components of the foaming composition. Singh also fails to teach the type of foam dispenser suitable for the invention therein.

Pregozen teaches the key ingredients that are used in personal hygiene wipe products such as baby wipes. See col. 2, lines 33-49; col. 5, lines 43-50.

Cocoamphodiacetate and polysorbate 20 are said to cleanse and soothes skin.

Disodium cocoamphodiacetate is disclosed the aqueous composition in Example 3.

See also propylene glycol and disodium EDTA dihydrate in the formulation. See instant claims 11, 12, 11, and 19.

Jorgensen is discussed above. Triethanolamine cocoyl glutamate is the preferred foaming agent. The invention is said to provide *ultra-mildness* to skin. See p. 2, [0001]-[0018].

Fowler, disclosed above, teaches personal cleansing foams in a manually actuated pump. The reference further teaches the weight range of surfactants, water, and foam stabilizers which overlap with the instant claims. See col. 2, line 59 – col. 3, line 42. See instant claims 2-7 and 11-14. The components used as foam stabilizers in the instant invention are referred as “humectants” in Fowler, which include glycerin and polyethylene glycol. See col. 10, line 41 – col. 11, line 22. See also examples for the preservatives in instant claims 18-20. Fowler further teaches using sponges or washcloths to form lathers and apply to the skin. See col. 2, lines 33 – 39; see instant claims 26 and 27. Although the specific weight ratio of the each of the surfactants are not disclosed, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Pregozen and Jorgensen, examiner views that one

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having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation.

Given the general teaching of foaming products for anorectal or colonic treatment in Singh, one having ordinary skill in the art would have looked to the prior arts such as Pregozen and Jorgensen for mild detergents that are suitable for the mucous membrane and skin.

It would have been also obvious to the one of ordinary skill in the art to have additionally provided, along with the foaming product, a conventional substrate to apply to the foaming product to the effected area of the body as a lather-forming device and for convenience to the users, as suggested by Fowler and Pregozen.

2. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh, Pregozen, and Jorgensen, as applied to claims 1-13, 17-25 above, and further in view of Fowler and Wenninger et al. (Int'l Cosmetic Ingredient Dictionary and Handbook, 1997) ("Wenninger")

Singh, Pregozen, Jorgensen, and Fowler are discussed above. Jorgensen teaches the use of thickeners in Example 3 in the amount of 1 % by weight. While Fowler teaches that gums may be added in the personal cleansing foam composition, the combined references fail to mention xanthan gum and the specific weight ratio of the components in claim 14 as required by instant claims. See col. 17, lines 29 – 35.

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Wenninger teaches xanthan gum is used to thicken an aqueous phase of cosmetic product. See pp. 1693 and 1695.

Given the general teaching of Jorgensen that thickeners may be added in the foaming composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have looked to the prior art such as Wenninger to for suitable thickening agents suitable for the aqueous composition. Selection of xanthan gum would have been obvious in view of Fowler which teaches the use of gums in the foaming composition.

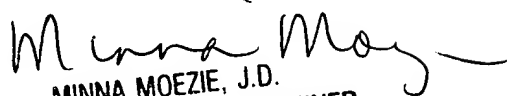
Examiner also views that one having ordinary skill in the art would have discovered the optimum or workable weight ranges of the components ranges by routine experimentation.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Gina C. Yu  
Patent Examiner  
March 24, 2002

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600